

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW MEXICO**

CRYSTAL VIGIL, AMY JONES, MELANIE) Case No. 1:16-cv-848
REID, MARY LIMBERICK, VICTORIA)
FENTY, ROSANA CONNELL, KATHRYN)
FREDRICKSON, STACEY CAMPBELL,) **JURY TRIAL DEMANDED**
SHELLY MCLEAN, THERESA)
MCELHONE, SERENA AAKER, KARIE)
BISHOP, FENNETA DELBRIDGE, TRACY)
EVANS, MELISSA THOMPSON, TIFFANY)
BIETZ, COURTNEY EVANS, CAROL)
BALDASARE, OLIVIA THOMPSON,)
PAMELA SCOTT, MELANIE JACKSON,)
ADENA EGAN, TINA JONES, YVETTE)
MIRANDA, EVA KILPATRICK, LACY)
BRADLEY, VANESSA KEY, WENDI)
YBARRA, JAYCE ORF, as individual)
Plaintiffs)
)
Plaintiffs,)
)
v.)
)
BAYER CORPORATION, BAYER)
HEALTHCARE LLC., BAYER ESSURE)
INC., BAYER HEALTHCARE)
PHARMACEUTICALS INC., BAYER A.G.,)
)
Defendants.)

NOTICE OF REMOVAL

Defendants Bayer Corporation, Bayer Essure Inc., Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. (together, “Bayer”) by and through their undersigned counsel, hereby provide notice pursuant to 28 U.S.C. §§ 1331, 1332, 1441, and 1446 of the removal of the above-captioned case from the Fourth Judicial District Court for the State of New Mexico to the United States District Court for the District of New Mexico. The grounds for removal are as follows:

1. On or about June 20, 2016, 29 unrelated Plaintiffs from 21 different states—all but one of whom have no apparent connection to New Mexico—filed a Complaint for Personal Injuries (“Complaint”) in New Mexico state court in this civil action styled *Vigil, et al. v. Bayer Corporation, et al.* The Complaint alleges that Plaintiffs suffered various injuries as a result of their individual experiences using Essure, an FDA-approved Class III medical device that serves as a form of permanent female birth control. *See* Ex. A (Complaint).

2. Essure was approved by FDA through the rigorous premarket approval (“PMA”) process in 2002. Ex. B (Premarket Approval Order). Since then, FDA has granted numerous supplemental approvals, including as recently as May 2016, *see* Ex. C (FDA website noting PMA Supplements), repeatedly reviewing and approving Essure’s design, construction, manufacturing, testing, training requirements, warnings, instructions for use, patient information, and all other labeling.

3. After a public hearing in September and months of investigation, FDA recently reaffirmed that “FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control.” Ex. D (FDA News Release (Feb. 29, 2016), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm488313.htm>).

4. In addition to this Notice of Removal, Bayer is filing a Motion to Dismiss and a Motion to Sever. The Motion to Dismiss demonstrates that this Court should dismiss the claims of the non-New Mexico Plaintiffs for lack of personal jurisdiction and under the doctrine of forum non conveniens, and that the Court should dismiss all of Plaintiffs’ claims as preempted and inadequately pled. The Motion to Sever shows that Plaintiffs’ claims should be severed because they are misjoined.

5. As set forth more fully below, this case is properly removed because this Court has both diversity jurisdiction and federal question jurisdiction. First, this Court has diversity jurisdiction because the amount in controversy with respect to each Plaintiff exceeds \$75,000 and complete diversity of citizenship exists between the sole proper Plaintiff and Defendants. Although several Plaintiffs allege that they are citizens of states in which a Defendant is a citizen, their misjoinder here does not defeat diversity jurisdiction. To the contrary, this Court should, as set forth in Bayer's Motion, dismiss the claims of these non-New Mexico Plaintiffs for lack of personal jurisdiction or under the *forum non conveniens* doctrine before determining whether complete diversity exists. *See Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 588 (1999). Indeed, in several recent cases involving similar circumstances, well-reasoned decisions of other courts have done precisely that. *See, e.g., Aclin v. PD-RX Pharms., Inc.*, 2016 WL 3093246, at *2 (W.D. Okla. June 1, 2016) (dismissing claims of out-of-state plaintiffs for lack of personal jurisdiction before considering whether complete diversity existed); *In re: Zofran (Ondansetron) Prods. Liab. Litig.*, 2016 WL 2349105, at *2-3 (D. Mass. May 4, 2016) (same). Once this Court dismisses the claims of the 28 non-New Mexico Plaintiffs, there is complete diversity between the remaining Plaintiff and Defendants. Alternatively, even if this Court considers subject matter jurisdiction before considering Bayer's Motion to Dismiss—which it need not and should not do—this Court should ignore the citizenship of non-New Mexico Plaintiffs because they are fraudulently joined and procedurally misjoined.

6. Second, this Court also has federal question jurisdiction. This case involves a medical device that was approved by FDA after receiving the highest level of scrutiny available in the federal regulatory system. Less than 1% of medical devices receive this rigorous federal approval. In addition, Essure has been subject to ongoing, intense review by the FDA, which

included public hearings addressing the same federal regulatory issues that form the premise of this lawsuit. Plaintiffs plead violations of federal law on the face of their Complaint. Plaintiffs' right to relief turns on resolution of the federal-law questions, and the exercise of federal question jurisdiction here will not disrupt the balance between state and federal jurisdiction, in light of the extraordinary federal involvement in the very issues that are at the heart of this case, and the small number of medical devices subject to such extraordinary federal oversight. *See Gilmore v. Weatherford*, 694 F.3d 1160, 1170-76 (10th Cir. 2012); *see also Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873, 878 (W.D. Tenn. 2013) (finding federal question jurisdiction because state-law product liability claims regarding PMA medical device required the court "to examine federal law, and, even more specifically, examine federal requirements imposed by the FDA through the premarket approval process"); *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 677-78 (S.D. Ohio 2014) (similar).

I. THE PROCEDURAL REQUIREMENTS OF REMOVAL ARE MET.

7. Pursuant to 28 U.S.C. § 1446(a) and Local Rule 81.1(a), true and correct copies of all process, pleadings, orders and other documents filed in the state court action are attached as Exhibit A.

8. Plaintiffs' Complaint was served on Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc., on June 23, 2016, and on Bayer Essure Inc. on June 27, 2016. 28 U.S.C. § 1446(b)(1) requires a notice of removal to be filed within 30 days of the service of a complaint upon the defendants. *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354 (1999) (30-day time limit for removal runs from date of formal service of the initial complaint). However, 30 days from June 23, 2016, was Saturday, July 23, 2016. Pursuant to Rule 6(a)(1)(C) of the Federal Rules of Civil Procedure, the period to file the Notice of Removal was extended to today, July 25, 2016. Accordingly, this Notice is timely filed.

9. Defendant Bayer AG has not yet been served in this matter. Nevertheless, all Defendants—each of which is represented by the undersigned—join in or consent to this Notice of Removal. *See* 28 U.S.C. § 1446(b)(2).¹

10. The United States District Court for the District of New Mexico presides in the locality in which the state court action is now pending. It is therefore a proper forum for removal. *See* 28 U.S.C. §§ 111, 1441(a).

11. No Defendant is a citizen of New Mexico, the state where this action was brought. *See id.* § 1441(b)(2).

12. A copy of this Notice of Removal is being served on Plaintiffs, and a copy is being filed with the state court. *See id.* § 1446(d).

13. If any questions arise about this removal, Bayer respectfully requests the opportunity to present briefing and oral argument in support of removal.

II. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1332 AND 1441.

14. A defendant may remove an action from state court to federal court if the action could have been brought originally in federal court. *See* 28 U.S.C. § 1441. Here, federal jurisdiction exists based upon diversity of citizenship pursuant to 28 U.S.C. § 1332, because this is a civil action between citizens of different states, and it is facially apparent that the amount in

¹ Bayer AG, which has not been served and which is represented by the undersigned, consents in this removal, but respectfully reserves all other rights. *See City of Clarksdale v. BellSouth Telecommc'ns., Inc.*, 428 F.3d 206, 214 n.15 (5th Cir. 2005) (“A defendant’s removal to federal court does not waive its right to object to service of process.”); *Rogers v. Amalgamated Transit Union Local 689*, 98 F. Supp. 3d 1, 5 (D.D.C. 2015) (unserved defendant who consented to removal did not waive objection to service of process); 14C Wright & Miller, et al., *Federal Practice and Procedure* § 3738 (4th ed. 2009) (“[D]efendants do not waive any defense by removing a case to federal court.”).

controversy with respect to each Plaintiff exceeds \$75,000, exclusive of interest and costs. *See id.* § 1332(a).

A. The Amount-In-Controversy Exceeds \$75,000.

15. Although Plaintiffs do not specifically allege the amount of damages in their Complaint, it is facially apparent that the damages sought, including any punitive damages, with respect to each of the Plaintiffs exceed \$75,000. *See* 28 U.S.C. § 1446(c)(2). A “defendant may rely on an estimate of the potential damages from the allegations in the complaint.” *McPhail v. Deere & Co.*, 529 F.3d 947, 955-56 (10th Cir. 2008). “A complaint that presents a combination of facts and theories of recovery that may support a claim in excess of \$75,000 can support removal.” *Id.* at 956.

16. Plaintiffs allege that they have sustained a wide variety of injuries including device migration, hysterectomy, abdominal pain, pelvic pain, back pain, weight gain, heavy menstrual bleeding, and perforated organs. Compl. ¶ 75.

17. Further, in support of their request for punitive damages, Plaintiffs allege that Bayer knew Essure was dangerous and ineffective, and withheld information from Plaintiffs, their physicians, the medical community, and the public at large. *See id.* ¶¶ 152-61. Courts have found the amount in controversy satisfied in similar cases, in which plaintiffs have asserted similar injuries, alleged similar degrees of pain, and requested punitive damages.²

² *See, e.g., In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig.*, 692 F. Supp. 2d 1025, 1040 (S.D. Ill. 2010) (“Given the severe and ongoing nature of the injuries alleged, the court finds that it is plausible and supported by the preponderance of the evidence that the amount in controversy has been established.”), *aff’d sub nom.* 643 F.3d 994 (7th Cir. 2011); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 2007 WL 2572048, at *5 (D. Minn. Aug. 30, 2007) (amount-in-controversy requirement satisfied where plaintiff alleged serious injuries from medical device and sought punitive damages, and other plaintiffs alleging injuries from same device plead damages in excess of \$75,000); *In re Rezulin Prods.*

18. Moreover—although Bayer denies that any relief is warranted—New Mexico New Mexico courts routinely uphold awards far in excess of \$75,000.00 for actual and punitive damages in personal injury actions, further supporting the conclusion that the jurisdictional minimum requirement is satisfied. *See, e.g., Alter v. Murphy Enters., Inc.*, 104 P.3d 1092 (N.M. Ct. App. 2004); *Methola v. County of Eddy*, 629 P.2d 350 (N.M. Ct. App. 1981). *See also Hollander v. Sandoz Pharms. Corp.*, 289 F.3d 1193, 1198 (10th Cir. 2002) (damages related to pharmaceutical product in excess of \$75,000); *McPhail v. Deere & Co.*, 529 F.3d 947, 953 (10th Cir. 2008) (citing *Luckett v. Delta Airlines, Inc.*, 171 F.3d 295, 298 (5th Cir. 1999) (finding it apparent from the face of the complaint that damages for property, travel expenses, an emergency ambulance trip, a six day stay in the hospital, pain and suffering, humiliation, and a temporary inability to do housework after hospitalization exceeded \$75,000)); *Gebbia v. Wal-Mart Stores, Inc.*, 233 F.3d 880, 883 (5th Cir. 2000) (finding it apparent from the face of the complaint that damages including medical expenses, physical and mental pain and suffering, loss of enjoyment of life, and permanent disability related to a slip-and-fall accident exceeded \$75,000); *Oja v. Howmedica, Inc.*, 111 F.3d 782, 785 (10th Cir. 1997) (discussing a jury award of \$896,921 in compensatory and \$896,921 in punitive damages). Indeed, Plaintiff’s “claim for punitive damages alone makes it virtually impossible to say that the claim is for less than the jurisdictional amount.” *Woodward v. Newcourt Commercial Fin. Corp.*, 60 F.Supp.2d 530, 532 (D.S.C. 1999).

Liab. Litig., 133 F. Supp. 2d 272, 296 (S.D.N.Y. 2001) (complaint alleging various injuries from prescription drug “obviously” met amount-in-controversy requirement).

19. Thus, given the nature of Plaintiffs' alleged injuries, the scope of damages sought, and the lack of any express limitation on the amount of damages sought, each Plaintiff's claim plainly satisfies the jurisdictional amount requirement.

B. Complete Diversity Of Citizenship Exists.

20. There is complete diversity of citizenship between the proper parties.

21. Defendant Bayer Corporation is an Indiana corporation with its principal place of business in Pennsylvania. Compl. ¶ 32. Thus, for diversity purposes, it is a citizen of Indiana and Pennsylvania. *See* 28 U.S.C. § 1332(c).

22. Plaintiffs allege that Defendant Bayer HealthCare LLC is incorporated in Delaware, that its principal place of business is in Pennsylvania, that its sole member is Bayer Corp., and that it has manufacturing operations in California. Compl. ¶ 33. Bayer HealthCare LLC is actually a limited liability company formed under the laws of Delaware. Its citizenship is determined by the citizenship of its nine members. *Zufelt v. Isuzu Motors Am., L.C.C.*, 727 F. Supp. 2d 1117, 1127 (D.N.M. 2009) (citing *Carden v. Arkoma Assocs.*, 494 U.S. 185, 195 (1990)). Those members are:

- a. Bayer Medical Care Inc., a Delaware corporation with its principal place of business in Pennsylvania;
- b. NippoNex Inc., a Delaware corporation with its principal place of business in New Jersey;
- c. Bayer West Coast Corporation, a Delaware corporation with its principal place of business in New Jersey;
- d. Bayer Essure Inc., a Delaware corporation with its principal place of business in New Jersey;
- e. Bayer Consumer Care Holdings LLC, a limited liability company, the sole common member of which is Bayer East Coast LLC and the sole preferred member of which is Bayer HealthCare US Funding LLC. Bayer East Coast LLC's sole member is Bayer US Holding LP, and Bayer HealthCare US Funding LLC's members are Bayer AG, Bayer Pharma AG, and Bayer

World Investments B.V. Bayer US Holding LP is a limited partnership in which Bayer World Investments B.V. is the sole General Partner and Bayer Solution B.V. is the sole Limited Partner. Both Bayer World Investments B.V. and Bayer Solution B.V. are incorporated in and have their principal places of business in the Netherlands. Bayer AG and Bayer Pharma AG are German corporations with their principal places of business in Germany;

- f. Dr. Scholl's LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;
- g. Coppertone LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC;
- h. MiraLAX LLC, a limited liability company, the sole member of which is Bayer HealthCare US Funding LLC; and
- i. Bayer HealthCare US Funding LLC, a limited liability company, whose members are Bayer AG, Bayer Pharma AG, and Bayer World Investments B.V. Bayer AG is a German corporation with its principal place of business in Germany; Bayer Pharma AG is a German corporation with its principal place of business in Germany; and Bayer World Investments B.V. is incorporated in and has its principal place of business in the Netherlands.

Accordingly, Bayer HealthCare LLC is a citizen of Delaware, New Jersey, Pennsylvania, Germany, and the Netherlands.

23. Plaintiffs allege that Defendant Bayer Essure Inc., is a Delaware corporation with its headquarters in California. Compl. ¶ 34. In fact, Bayer Essure Inc. is a Delaware corporation whose principal place of business has been in New Jersey since April 21, 2016. Accordingly, it is a citizen of Delaware and New Jersey for diversity purposes. *See* 28 U.S.C. § 1332(c).

24. Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey. Compl. ¶ 35. Thus, for diversity purposes, it is a citizen of Delaware and New Jersey. *See* 28 U.S.C. § 1332(c).

25. Bayer A.G. is a German corporation with its principal place of business in Germany. Compl. ¶ 36. Thus, for diversity purposes, it is a citizen of Germany. *See* 28 U.S.C. § 1332(c).

26. The 29 unrelated Plaintiffs allege that they are citizens of 21 different States: Arkansas, California, Colorado, Illinois, Indiana, Kentucky, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Jersey, New Mexico, New York, North Carolina, Ohio, Pennsylvania, Tennessee, Texas, Virginia, and Washington. Compl. ¶¶ 2-30. Specifically:

- a. Plaintiff Melanie Jackson is a citizen of Arkansas, *id.* ¶ 19;
- b. Plaintiff Fennetta Delbridge is a citizen of California, *id.* ¶ 6;
- c. Plaintiff Melanie Reid is a citizen of Colorado, *id.* ¶ 27;
- d. Plaintiff Pamela Scott is a citizen of Illinois, *id.* ¶ 18;
- e. Plaintiff Adena Egan is a citizen of Indiana, *id.* ¶ 5;
- f. Plaintiff Stacey Campbell is a citizen of Kentucky, *id.* ¶ 7;
- g. Plaintiff Karie Bishop is a citizen of Kentucky, *id.* ¶ 10;
- h. Plaintiff Kathryn Fredrickson is a citizen of Maryland, *id.* ¶ 16;
- i. Plaintiff Courtnie Evans is a citizen of Massachusetts, *id.* ¶ 14;
- j. Plaintiff Shelly McLean is a citizen of Michigan, *id.* ¶ 8;
- k. Plaintiff Victoria Fenty is a citizen of Minnesota, *id.* ¶ 29;
- l. Plaintiff Rosana Connell is a citizen of Minnesota, *id.* ¶ 30;
- m. Plaintiff Jaycee Orf is a citizen of Missouri, *id.* ¶ 25;
- n. Plaintiff Amy Jones is a citizen of Missouri, *id.* ¶ 26;
- o. Plaintiff Yvette Miranda is a citizen of New Jersey, *id.* ¶ 3;
- p. Plaintiff Carol Baldasare is a citizen of New Jersey, *id.* ¶ 15;
- q. Plaintiff Crystal Vigil is a citizen of New Mexico, *id.* ¶ 2;
- r. Plaintiff Tina Jones is a citizen of New York, *id.* ¶ 20;

- s. Plaintiff Eva Kilpatrick is a citizen of New York, *id.* ¶ 21;
- t. Plaintiff Melissa Thompson is a citizen of North Carolina, *id.* ¶ 12;
- u. Plaintiff Vanessa Key is a citizen of North Carolina, *id.* ¶ 22;
- v. Plaintiff Tracy Evans is a citizen of Ohio, *id.* ¶ 11;
- w. Plaintiff Olivia Thompson is a citizen of Ohio, *id.* ¶ 17;
- x. Plaintiff Theresa McElhone is a citizen of Pennsylvania, *id.* ¶ 4;
- y. Plaintiff Serena Aaker is a citizen of Tennessee, *id.* ¶ 9;
- z. Plaintiff Tiffany Bietz is a citizen of Texas, *id.* ¶ 13;
- aa. Plaintiff Lacy Bradley is a citizen of Virginia, *id.* ¶ 24;
- bb. Plaintiff Mary Limberick is a citizen of Virginia, *id.* ¶ 27;
- cc. Plaintiff Wendi Ybarra is a citizen of Washington, *id.* ¶ 23;

27. Only one Plaintiff, Crystal Vigil, alleges that she is a citizen of New Mexico. The remaining 28 Plaintiffs allege no connection whatsoever to New Mexico.

28. A handful of Plaintiffs allege that they are citizens of Defendants' home states. But those Plaintiffs allege no connection with the New Mexico Plaintiff, do not base their claims on any conduct or injuries that occurred in New Mexico, and do not otherwise allege any kind of connection to New Mexico.

29. The presence of the non-diverse Plaintiffs among the non-New Mexico Plaintiffs does not destroy diversity jurisdiction for two distinct reasons:

First, this Court should exercise its discretion to consider personal jurisdiction and forum non conveniens at the threshold, and grant Bayer's Motion to Dismiss the claims of the non-New Mexico Plaintiffs—including the non-diverse Plaintiffs—under these doctrines. Once the non-New Mexico Plaintiffs claims are dismissed, complete diversity exists between the sole New Mexico Plaintiff and Defendants. Moreover, as shown in the Motion to Dismiss, all Plaintiffs'

claims—including those of the New Mexico Plaintiff—also fail as a matter of law because they are preempted and inadequately pled.

Second, in the alternative, the citizenship of the non-New Mexico Plaintiffs—including the non-diverse Plaintiffs—poses no impediment to diversity under the doctrines of procedural misjoinder and fraudulent joinder, even if this court considers jurisdiction before it considers the Motion to Dismiss. Thus, this Court may grant Bayer’s Motion to Sever the various Plaintiffs’ claims and remand only the claims of any non-diverse Plaintiffs that this Court does not otherwise dismiss.

1. There is complete diversity between the proper parties because this Court lacks personal jurisdiction over the non-New Mexico Plaintiffs’ claims.

30. The Supreme Court has made clear that courts may consider a motion to dismiss for lack of personal jurisdiction before considering a motion to remand for lack of subject matter jurisdiction, especially if the personal jurisdiction question is “straightforward” and the subject matter jurisdiction question is “difficult and novel.” *Ruhrgas*, 526 U.S. at 588; *accord Gadlin v. Sybron Int’l Corp.*, 222 F.3d 797, 799 (10th Cir. 2000). Thus, where it is clear that the court lacks personal jurisdiction over non-diverse plaintiffs’ claims, there is no need to consider the doctrine of procedural misjoinder or fraudulent joinder: the court should *first* dismiss the non-diverse plaintiffs’ claims for lack of personal jurisdiction and *then*—in light of the diversity between the remaining plaintiffs and defendants—deny the motion to remand. *See, e.g., Cantor Fitzgerald, L.P. v. Peaslee*, 88 F.3d 152, 153 (2d Cir. 1996); *Villar v. Crowley Maritime Corp.*, 990 F.2d 1489, 1494-95 (5th Cir. 1993), *cert. denied* 510 U.S. 1044 (1994); *Aclin*, 2016 WL 3093246, at *2; *Zofran*, 2016 WL 2349105, at *2-3; *Kraft v. Johnson & Johnson*, 97 F. Supp. 3d 846, 854-55 (S.D. W.Va. 2015); *Wolstenholme v. Bartels*, 2011 WL 4359989, at *1 n.1 (E.D. Pa. Sept. 19, 2011), *aff’d*, 511 F. App’x 215 (3d Cir. 2013); *Foslip Pharm., Inc. v. Metabolife Int’l*,

Inc., 92 F. Supp. 2d 891, 899 (N.D. Iowa 2000); *Martino v. Viacao Aerea Riograndense, S.A.*, 1991 WL 13886, at *4 (E.D. La. Jan. 25, 1991); *Nolan v. Boeing Co.*, 736 F. Supp. 120, 127 (E.D. La. 1990).

31. This Court should take the “easier route.” *Air Century SA v. Atlantique Air Assistance*, 447 F. App’x 879, 881 (10th Cir. 2011). Here, the easier route is to dismiss for lack of personal jurisdiction without reaching more difficult questions of procedural misjoinder and fraudulent joinder. *See Aclin*, 2016 WL 3093246, at *2 (“The personal jurisdiction question presents straightforward issues regarding the sufficiency of contacts and the consequences of registration to do business. Conversely, subject-matter jurisdiction presents complex issues, including the doctrine of fraudulent misjoinder, a doctrine the Tenth Circuit has twice declined to adopt or reject.”); *Kraft*, 97 F. Supp. 3d at 850-51 (describing fraudulent misjoinder as “relatively recent and untested”). This Court should therefore consider the personal jurisdiction issue first.

32. The personal jurisdiction question is “straightforward,” *Ruhrgas*, 526 U.S. at 588; *Aclin*, 2016 WL 3093246, at *2, since this Court plainly lacks either general or specific personal jurisdiction over Bayer with respect to the non-New Mexico Plaintiffs’ claims.

33. Personal jurisdiction may be general or specific. General jurisdiction covers claims “unrelated to the defendant’s contacts with the forum state,” and exists when the defendant’s contacts unrelated to the claims at issue are so “continuous and systematic” as to render the defendant “essentially at home” in the forum state. *See Daimler AG v. Bauman*, 134 S. Ct. 746, 760-61 & n.19 (2014); *Am. Fidelity Assurance Co. v. Bank of N.Y. Mellon*, 810 F.3d 1234, 1240-41 (10th Cir. 2016); *see also Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564

U.S. 915, 919-20 (2011); *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 415-16 (1984).

34. Here, there is no general personal jurisdiction because no Defendant is incorporated in New Mexico, has its principal place of business in New Mexico, or has such continuous and systematic ties to New Mexico as to render it “at home” in New Mexico. *Daimler*, 134 S. Ct. at 760-61 & n.19. To the extent that Plaintiffs suggest that general jurisdiction exists because Bayer “is authorized to and does business” in New Mexico, Compl. ¶¶ 1, 32-36, that is plainly insufficient under *Daimler*. See *Daimler*, 134 S. Ct. at 761 (no general jurisdiction in a state based on defendant’s “sizable sales” in that state); *Aclin*, 2016 WL 3093246, at *6 (“The [Supreme] Court has repeatedly rejected arguments suggesting that substantial commercial activity alone would be sufficient for general jurisdiction.”); see also *Zofran*, 2016 WL 2349105, at *3 (holding that marketing and selling products in forum state was insufficient to establish general jurisdiction in forum state).

35. Specific personal jurisdiction exists only if a defendant has sufficient “‘minimum contacts’ with the forum state, such that having to defend a lawsuit there would not ‘offend traditional notions of fair play and substantial justice.’” *Dudnikov v. Chalk & Vermilion Fine Arts, Inc.*, 514 F.3d 1063, 1070 (10th Cir. 2008) (quoting *Int’l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945)). Unlike general jurisdiction, specific jurisdiction “depends ‘on the relationship among the defendant, the forum, and the litigation.’” *Anzures v. Flagship Restaurant Grp.*, 819 F.3d 1277, 1280 (10th Cir. 2016) (quoting *Walden v. Fiore*, 134 S. Ct. 1115, 1121 (2014)).

36. Bayer is not subject to specific personal jurisdiction with respect to the claims of the non-New Mexico Plaintiffs (including all non-diverse Plaintiffs). None of these Plaintiffs’

injuries arise out of or relate to any conduct or transaction that occurred in New Mexico. *Id.* at 1281 (no specific jurisdiction where defendant's contacts in the forum state were "not the subject matter of the case, so they [were] not jurisdictionally related to the tort claims"). The non-New Mexico Plaintiffs cannot piggyback off the specific personal jurisdiction that exists for the one New Mexico Plaintiff. *See Tulsa Cancer Inst., PLLC v. Genentech Inc.*, 2016 WL 141859, at *3 (N.D. Okla. Jan. 12, 2016); *In re Testosterone Replacement Therapy Prods. Liab. Litig.*, 2016 WL 640520, at *5-6 (N.D. Ill. Feb. 18, 2016); *Turi v. Main Street Adoption Servs., LLP*, 2009 WL 2923248, at *13 (E.D. Mich. Sept. 9, 2009), *aff'd in part, rev'd in part, and remanded on other grounds*, 633 F.3d 496 (6th Cir. 2011).

37. Because Bayer is not subject to personal jurisdiction in New Mexico with respect to the non-New Mexico Plaintiffs' claims, those claims (and those Plaintiffs) should be dismissed. The remaining Plaintiff resides in New Mexico, a State in which no Defendant is a citizen. *See* 28 U.S.C. § 1332(c). Accordingly, this Court has diversity jurisdiction over the proper parties' claims.

2. There is complete diversity between the proper parties because the non-New Mexico Plaintiffs' claims should be dismissed under the doctrine of forum non conveniens.

38. Alternatively, this Court also may exercise its discretion to dismiss the non-New Mexico Plaintiffs' claims under the doctrine of forum non conveniens before considering whether complete diversity exists. *Sinochem Int'l Co. Ltd. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 436 (2007) ("[W]here subject-matter or personal jurisdiction is difficult to determine, and *forum non conveniens* considerations weigh heavily in favor of dismissal, the court properly takes the less burdensome course."); *Iwag v. Geisel Compania Maritima, S.A.*, 882 F. Supp. 597, 602 (S.D. Tex. 1995) (recognizing that "a district court sitting in diversity jurisdiction [may] decide a motion to dismiss for forum non conveniens before a motion to remand"). Forum non

conveniens applies where (1) “there is an adequate alternative forum in which the defendant is amenable to process” and the alternative forum’s law applies, and (2) public and private interest factors favor dismissal. *Yavuz v. 61 MM, Ltd.*, 576 F.3d 1166, 1172 (10th Cir. 2009). Both of these factors are met.

39. Each non-New Mexico Plaintiff has an adequate alternative forum in her home state where that the home state’s law would apply.

40. The balance of private and public interest factors demonstrates that dismissal is appropriate here. The private interest factors include ease of access to and cost of obtaining witnesses, as well as other practical problems. The public interest factors include avoiding court congestion, the interest in having localized controversies decided locally, the interest in having trial in a forum that is at home with the applicable law, the interest in avoiding conflict of laws questions, and the unfairness of burdening New Mexico citizens with jury duty to decide claims unrelated to New Mexico. *See Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 241 n.6 (1981).

41. The non-New Mexico Plaintiffs’ claims should be dismissed because (1) those claims are likely to require the presence of physician witnesses who are not located in New Mexico, (2) there is no reason to burden New Mexico courts and jurors with 28 sets of claims involving non-New Mexico Plaintiffs who allegedly suffered injuries outside of New Mexico, and (3) dismissing claims of non-New Mexico Plaintiffs will avoid the need to resolve numerous conflict of laws issues.

42. Thus, this Court should dismiss the non-New Mexico Plaintiffs’ claims under the doctrine of forum non conveniens, and find complete diversity between the remaining Plaintiff and Defendants.

3. There is complete diversity because the non-New Mexico Plaintiffs are procedurally misjoined.

43. The non-diverse Plaintiffs also do not destroy diversity jurisdiction because they are procedurally misjoined.

44. Under the doctrine of procedural misjoinder, courts disregard the citizenship of misjoined parties. *See Tapscott v. MS Dealer Serv. Corp.*, 77 F.3d 1353, 1359 (11th Cir. 1996), *abrogated on other grounds by Cohen v. Office Depot, Inc.*, 204 F.3d 1069 (11th Cir. 2000); *Ullman v. Safeway Ins. Co.*, No. CIV 13-0595 JB/RHS, 2013 WL 7141522, *31 (D.N.M. Dec. 31, 2013); *Flores-Duenas v. Briones*, No. CIV 13-0660 JB/CG, 2013 WL 6503537 (D.N.M. Dec. 1, 2013). Misjoinder occurs when joined claims do not both (1) “aris[e] out of the same transaction, occurrence, or series of transactions or occurrences,” and (2) involve “any question of law or fact common to all plaintiffs.” Fed. R. Civ. P. 20(a); *In re Rezulin Prods. Liab. Litig.*, 168 F. Supp. 2d 136, 144 (S.D.N.Y. 2001) (“Misjoinder of parties occurs when a party fails to satisfy the conditions for permissive joinder under Rule 20(a).”).

45. Here, as shown above, the non-New Mexico Plaintiffs are procedurally misjoined because of the clear and indisputable lack of personal jurisdiction. *In re: Zofran*, 2016 WL 2349105, at *2 (noting that lack of personal jurisdiction may be a basis for finding procedural misjoinder). In light of *Daimler*, *Anzures*, and the other cases cited above, the lack of personal jurisdiction with respect to the non-New Mexico Plaintiffs’ claims is palpable, and this Court may therefore conclude that their inclusion in this Complaint amounts to procedural misjoinder.

46. The misjoinder here is particularly egregious for the additional reason that the various Plaintiffs’ claims do not “aris[e] out of the same transaction, occurrence, or series of transactions or occurrences.” *See* Fed. R. Civ. P. 20. To the contrary, Essure is a highly

regulated medical device that is available only through a patient's prescribing physician. The far-flung Plaintiffs joined together in this litigation had their devices placed at various different times, in different states, and in different circumstances, and they allegedly suffered separate and distinct injuries.

47. The only possible connection in the Plaintiffs' various experiences is that they all involve the same prescription medical device. But "[a] multitude of cases around the country have held that plaintiffs were not properly joined when the only common link among them was a defective drug or medical device." *Stinnette v. Medtronic Inc.*, 2010 WL 767558, at *2 (S.D. Tex. Mar. 3, 2010) (citing *In re Rezulin*, 168 F. Supp. 2d at 145-46; *Graziose v. Am. Home Prods. Corp.*, 202 F.R.D. 638, 640 (D. Nev. 2001)); see, e.g., *In re Propecia (Finasteride) Prod. Liab. Litig.*, 2013 WL 3729570, at *3 (E.D.N.Y. May 17, 2013) (allowing removal from state court; case transferred to MDL); *In re Fosamax*, 2012 WL 1118780, at *4 (rejecting joinder of claims against the manufacturers and seller of the same drug); *Alday v. Organon USA, Inc.*, 2009 WL 3531802, at *1 (E.D. Mo. Oct. 27, 2009) (finding misjoinder where "[e]ach [p]laintiff was injured at different times in different states allegedly from their use of [the product] that was presumably prescribed by different healthcare providers"); *In re Seroquel Prods. Liab. Litig.*, 2006 WL 3929707, at *4 (M.D. Fla. Dec. 22, 2006) ("Because these multiple plaintiff cases do not appear to seek relief arising from the same transaction or occurrence, severance of the individual plaintiffs is proper."), *adopted*, 2007 WL 219989 (M.D. Fla. Jan. 26, 2007); *In re Baycol Prods. Liab. Litig.*, 2002 WL 32155269, at *2 (D. Minn. July 5, 2002) (finding joinder improper based on the "many differences between the unique histories of each plaintiff"); *In re Diet Drugs*, 1999 WL 554584, at *3 (E.D. Pa. July 16, 1999) (holding multiple plaintiffs alleging damages in a single case arising from ingestion of diet drugs were "clearly misjoined" under Fed.

R. Civ. P. 20(a)); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 1995 WL 428683, at *6 (E.D. Pa. July 17, 1995) (“[J]oinder based on the belief that the same occurrence or transaction is satisfied by the fact that claimants have the same or similar device of a defendant manufacturer implanted in or about their spine is . . . not a proper joinder . . .”).

48. Severance is particularly appropriate here in light of the disparate factual and legal issues that pertain to each Plaintiff. Each Plaintiff’s claim will be dominated by distinctive factual issues, such as the specific details of each Plaintiff’s Essure procedure, each Plaintiff’s medical history prior to that procedure, the type and nature of the injuries each Plaintiff allegedly suffered, causation of those injuries, the training and performance of each Plaintiff’s physician, each Plaintiff’s and her physician’s reliance on alleged misrepresentations, and each Plaintiff’s and her physician’s consideration of the Essure labeling and warnings that existed at the times of each Plaintiff’s alleged injuries. Similarly, each Plaintiff’s claim will involve disparate legal questions unique to the law of 21 separate jurisdictions, such as elements of common law actions, the learned intermediary doctrine, the availability of punitive damages, and the length of applicable statutes of limitations.

4. There is complete diversity because the non-New Mexico Plaintiffs are fraudulently joined.

49. In the alternative, the Court also should disregard the citizenship of the non-diverse Plaintiffs because they are fraudulently joined. *See Zufelt v. Isuzu Motors Am., LCC*, 727 F. Supp. 2d 1117, 1129 (D.N.M. 2009) (fraudulent joinder may be based on lack of personal jurisdiction when personal jurisdiction is not waived).

50. As set forth above, there is no reasonable basis under which the non-New Mexico Plaintiffs may subject Bayer to general or specific personal jurisdiction in New Mexico. Because the only plausible basis for including these non-New Mexico Plaintiffs in this action is

to destroy diversity jurisdiction, this Court should apply the doctrine of fraudulent joinder and find complete diversity of citizenship.

III. REMOVAL IS PROPER BECAUSE THIS COURT HAS SUBJECT MATTER JURISDICTION PURSUANT TO 28 U.S.C. §§ 1331 AND 1441.

51. This Court also has federal question jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1441.

52. Federal question jurisdiction exists where a plaintiff pleads federal violations on the face of the complaint and “the vindication of a right under state law necessarily turn[s] on some construction of federal law.” *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986) (quoting *Franchise Tax Bd. v. Construction Laborers Vacation Trust*, 463 U.S. 1, 9 (1983)). This “captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 312 (2005). “[T]he question is, does a state-law claim necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Id.* at 314.

53. Thus, federal question jurisdiction exists where a state- law claim “(1) must necessarily raise a federal claim that is both (2) actually disputed and (3) substantial; and (4) that may be resolved in a federal forum without disturbing the balance of federal and state judicial responsibilities.” *Devon Energy Prod. Co., L.P. v. Mosaic Potash Carlsbad, Inc.*, 693 F.3d 1195, 1208 (10th Cir. 2012). These factors are met here, in the context of a PMA medical device that FDA heavily regulates, as other well-reasoned cases have held. *See Jenkins v. Medtronic, Inc.*, 984 F. Supp. 2d 873, 878 (W.D. Tenn. 2013) (finding federal question jurisdiction over

state-law product liability claims regarding PMA medical device because claims required court to decide questions of federal law); *H.R. ex rel. Reuter v. Medtronic, Inc.*, 996 F. Supp. 2d 671, 677-78 (S.D. Ohio 2014) (similar); *cf. Bowdrie v. Sun Pharm. Indus. Ltd.*, 909 F. Supp. 2d 179, 184-85 (E.D.N.Y. 2012) (finding federal question jurisdiction in product liability drug case where “boundaries of Plaintiffs’ claims . . . are established by the FDCA”).

54. Here, Plaintiffs’ claims turn on whether Defendants violated federal regulatory requirements. *See* § III.A, *infra*. Moreover, FDA’s recent investigation into and response to the very issues that are the subject of this case renders the federal interest particularly substantial and warrants the exercise of federal jurisdiction to resolve the overwhelmingly federal issues of law at issue in this case. *See* Compl. ¶¶ 69-74.

A. Plaintiffs’ Right To Relief Depends On The Resolution Of Substantial And Disputed Federal Questions.

55. Plaintiffs predicate their state-law claims on numerous alleged violations of federal requirements that they plead directly in their Complaint. For example, Plaintiffs allege that Bayer:

- a. “violated [its] duty of care with regard to specifications and protocols set forth in federal regulations, PMA, Supplements, and/or the [PMA] Conditions of Approval ” Compl. ¶ 79;
- b. “violated federal law in the manufacture of Essure,” *id.* ¶ 81;
- c. “failed to . . . fil[e] PMA supplements, update[e] [Essure’s] label pursuant to 21 C.F.R. § 820.39(d), or submit[] MDRs,” *id.* ¶ 105;
- d. “manufactur[ed] actual Essure® devices that differ from the specifications set forth in the PMA, its Supplements, the Conditions of Approval and/or other federal regulations,” *id.* ¶ 119;
- e. “failed to manufacture the Essure® devices consistent with federal requirements,” *id.* ¶ 120;

- f. “violated federal law and/or were cited by the FDA for [federal violations],” *id.* ¶ 125;
- g. disseminated false information in violation of the PMA, 21 U.S.C. § 352(q), and 21 C.F.R. § 814.80, *id.* ¶ 135.

56. These allegations of federal violations are not tangential: Plaintiffs’ right to relief “depends on” their resolution. *Gilmore*, 694 F.3d at 1170. As part of the Medical Device Amendments, Congress adopted a “general prohibition on non-Federal regulation” of medical devices, H.R. Rep. No. 94-853, at 45 (1976), by expressly preempting “any requirement” imposed by state law relating to the safety or effectiveness of a medical device that “is different from, or in addition to, any requirement applicable . . . to the device” under federal law. 21 U.S.C. § 360k(a). As the Supreme Court held in *Riegel v. Medtronic, Inc.*, premarket approval of a Class III medical device establishes federal requirements applicable to that device, and state-law tort claims impose state-law requirements. 552 U.S. 312, 321-25 (2008). Thus, to the extent state-law claims rest on duties “different from, or in addition to” federal requirements, they are expressly preempted. *Id.* at 330. As the Eighth Circuit has explained, a “plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)).” *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010)) (emphasis omitted); *see also Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1342 (10th Cir. 2015) (dismissal of claims required because plaintiff failed to “identif[y] any legally viable federal requirement that might parallel and thus permit her claims”). Thus, Plaintiffs cannot succeed on their state-law claims unless they show that Bayer violated a federal requirement. *See Gilmore*, 694 F.3d at 1176 (finding federal question jurisdiction where plaintiffs “cannot win unless the court answers [the] [federal] question[s]” in their favor).

57. It is no answer to suggest that the federal-law questions arise only in the context of a preemption defense. In rejecting a similar attempt to defeat federal question jurisdiction,

another court explained that “Plaintiffs have set the landscape and scope of the issues that would be addressed in this case,” and the fact that “Defendants have properly asserted an applicable preemption defense to Plaintiffs’ claims” does not deprive the court of jurisdiction. *Jenkins*, 984 F. Supp. 2d at 880. Here as well, Plaintiffs “set the landscape” when they pleaded violations of federal law on the face of their own Complaint.

58. FDA’s involvement in this matter is extraordinary: it not only has conducted the usual stringent PMA review, but FDA also has specifically investigated *the very matters* that are the subject of Plaintiffs’ claims and made a determination earlier this year that Essure remains “an appropriate option for the majority of women seeking a permanent form of birth control.” FDA News Release (Feb. 29, 2016) (Ex. D). That federal involvement here is crucial. *Gilmore*, 694 F.3d at 1174 (“The involvement of the federal government in [the] dispute is a key factor.”). Plaintiffs are seeking to second-guess this federal law determination by a federal agency. Permitting the inherently federal claims at issue here to be addressed in a federal forum properly recognizes and protects the significant federal interest in this case. Indeed, “[t]here can be little doubt that this dispute is far more material to the federal government than” a typical product liability claim. *Id.* at 1175.

B. Federal Jurisdiction Will Not Disrupt the Federal-State Balance.

59. For similar reasons, the exercise of federal jurisdiction will not disrupt the balance between federal and state law that Congress has created. Federal jurisdiction here would “portend only a microscopic effect on the federal-state division of labor”—namely, those cases in which FDA has taken specific steps to address the alleged issues that are the subject of Plaintiffs’ Complaint. *Id.* at 1176 (quoting *Grable*, 545 U.S. at 315). At the same time, federal

question jurisdiction will permit a federal court to decide important and necessarily federal issues of law. *See Reuter*, 996 F. Supp. 2d at 680.

60. Accordingly, this Court should exercise federal question jurisdiction here.

CONCLUSION

WHEREFORE, Notice is given that this action is removed from the Fourth Judicial District Court of the State of New Mexico to the United States District Court for the District of New Mexico.

DATED: July 25, 2016

Respectfully submitted,

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Jennifer G. Anderson
Jennifer G. Anderson
Alex C. Walker
P.O. Box 2168
500 Fourth St. NW, Ste. 1000
Albuquerque, NM 87103-2168
Tel: 505-848-1800
jga@modrall.com
awalker@modrall.com

SIDLEY AUSTIN LLP
Jonathan F. Cohn
(*pro hac vice* motion to be filed)
Rebecca K. Wood
(*pro hac vice* motion to be filed)
1501 K Street, N.W.
Washington, DC 20005
Telephone: 202-736-8000
jfcohn@sidley.com
rwood@sidley.com

SIDLEY AUSTIN LLP

Maja C. Eaton
(*pro hac vice* motion to be filed)
One S. Dearborn St.
Chicago, IL 60603
Telephone: (312) 853-7000
meaton@sidley.com

Attorney for Defendants Bayer Corporation, Bayer HealthCare LLC, Bayer Essure Inc., and Bayer HealthCare Pharmaceuticals Inc.

WE HEREBY CERTIFY that on the 25th day of July, 2016, we filed the foregoing electronically through the CM/ECF system and served the following counsel via electronic mail:

Kate Ferlic
Brian Egolf
EGOLF + FERLIC + HARWOOD, LLC
123 W. San Francisco St., Suite 200
Santa Fe, NM 87501
Tel: 505-986-9641
kate@egolfaw.com
brian@egolfaw.com

Holly Kelly Ennis
ENNIS & ENNIS, P.A.
1101 Pennsylvania Ave., NW, 3rd Floor
Washington, DC 20004
Tel: 800-856-6405
hckennis@ennislaw.com

G. Sean Jez
Jessica A. Kasischke
David Hobbs
FLEMING | NOLEN | JEZ, LLP
2800 Post Oak Blvd., Suite 4000
Houston, Texas 77056
Tel: 713-621-7944
Sean_jez@fleming-law.com
Jessica_Kasischke@fleming-law.com
David_Hobbs@fleming-law.com

Attorneys for Plaintiffs

MODRALL, SPERLING, ROEHL, HARRIS
& SISK, P.A.

By: /s/ Alex Walker
Alex C. Walker

W2752656.DOCX